REMARKS

The Office Action of October 2, 2002 has been carefully considered and reconsideration of the application as amended in view of the following remarks is respectfully requested.

Claims 24-38 are pending in this application.

The rejection of the claims under 35 U.S.C. § 112, first paragraph, has been maintained, allegedly "as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention".

The Action also notes that Applicants' submission of a translated version of a foreign document to obviate the rejection is not permitted on the ground that "incorporation of essential material into the specification by reference to a foreign application or patent, or to a publication, is improper". (MPEP (608.01)).

Applicants do not contest that essential material may not be incorporated into the specification by reference to a foreign publication.

However, Applicants are not seeking to incorporate any subject matter into the specification. Applicants instead have brought to the Examiner's attention references intended only to show that which one skilled in the art would have known at the time the application was filed. Applicants respectfully direct the Examiner's attention to the first full paragraph on page 6 of Applicants' response mailed June 10, 2002 wherein it is stated that "By submission of the enclosed proofs, the Applicants have met their burden in demonstrating that one skilled in the art would have been familiar with the medical grade polyacrylamide gel so that further description in the specification of this material should not be required".

In accordance with MPEP § 2164.05, "Once the Examiner has... established a reasonable basis to question the enablement provided..., the burden falls on the Applicant to present persuasive arguments, supported by suitable proofs where necessary, that one skilled in the art would be able to make and use the claimed invention using the application as a guide". It is further stated that: "The evidence provided by the Applicant need not be conclusive but merely convincing to one skilled in the art. Applicant may submit factual affidavits... or cite references to show what one skilled in the art knew at the time of filing the application".

As stated in MPEP § 2164.05(a): The specification need not disclose what is well-known to those skilled in the art and preferably omits that which is well-known to those

skilled and already available to the public".

It is respectfully submitted that the copies of the Russian patent and other publications, published before the filing date of the subject application, and the English translation of the relevant portions of the Russian patent, and also the affidavit submitted to attest to the accuracy of the translation of the portions of the Russian patent, enclosed with Applicants' responses mailed on June 10, 2002 and July 8, 2002, respectively, successfully demonstrate that one skilled in the art would have known not only to employ polyacrylamide gel for medical purposes but, accordingly, the nature or type of the polyacrylamide gel to use, and that no further description of the polyacrylamide gel in the specification as filed should have been required.

Applicants enclose herewith copies of additional references, U.S. Patent Nos. 4,975,377 and 4,898,824, well-known to those skilled in the art, published on December 4, 1990 and February 6, 1990, respectively, which provide further proofs to establish that the skilled person was using cross-linked polyacrylamide gel for biological purposes before the filing date of the subject application.

Also submitted herewith is a copy of information obtained from the Bioform Research Centre website which provides additional proof of the development and use of polyacrylamide gel for medical purposes over decades, prior to the filing date of the subject application, and descriptions of other medical uses for such polyacrylamide gel.

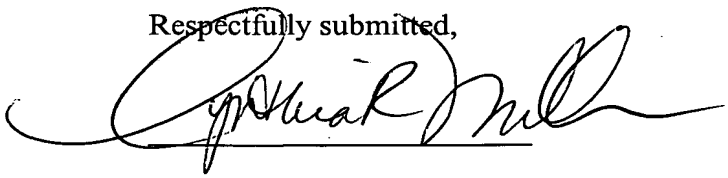
Further submitted herewith is a true copy of an extract and an English translation thereof from Minutes No. 9 of the Committee for New Medical Engineering of the Ministry of Health of the Russian Federation, indicating that the claimed method has been approved for clinical trials. Although published October 22, 2002, after the filing date of this application, the document provides indirect support that the polyacrylamide gel used in the invention has a medical purpose but also that those skilled in the art have considered the invention and have deemed the claimed invention to be operable and deserving of further clinical investigation.

It is respectfully submitted that Applicants' burden under 35 U.S.C. § 112, first paragraph, has been met and it is requested that the rejection be withdrawed.

Favorable consideration is respectfully requested.

A petition and fee for extension of time for two months is submitted herewith.

Respectfully submitted,



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